

IP7 Rec'd PCT/PTO 26 APR 2006

PTO-1390 (Rev. 07-2005)

Approved for use through 3/31/2007. OMB 0651-0021  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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|   |  |   |
|---|--|---|
| <b>TRANSMITTAL LETTER TO THE UNITED STATES<br/>DESIGNATED/ELECTED OFFICE (DO/EO/US)<br/>CONCERNING A SUBMISSION UNDER 35 U.S.C. 371</b>   |  | ATTORNEY'S DOCKET NUMBER<br><b>701039-53522</b><br>U.S. APPLICATION NO. [blank], [blank] (see 37 CFR 1.5)<br><b>10/577167</b> |
| INTERNATIONAL APPLICATION NO.<br><b>PCT/US2004/035874</b>   | INTERNATIONAL FILING DATE<br><b>28 October 2004 (28.10.2004)</b> | PRIORITY DATE CLAIMED<br><b>29 October 2003 (29.10.2003)</b>  |
| TITLE OF INVENTION METHOD OF INHIBITING REJECTION FOLLOWING ORGAN TRANSPLANTATION   |  |   |
| APPLICANT(S) FOR DO/EO/US BRISCOE, David M., et al.   |  |   |
| Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:   |  |   |
| 1. <input checked="" type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a submission under 35 U.S.C. 371.<br>2. <input type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a submission under 35 U.S.C. 371.<br>3. <input checked="" type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.<br>4. <input checked="" type="checkbox"/> The US has been elected (Article 31).<br>5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2))<br>a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).<br>b. <input type="checkbox"/> has been communicated by the International Bureau.<br>c. <input checked="" type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).<br>6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).<br>a. <input type="checkbox"/> is attached hereto.<br>b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).<br>7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))<br>a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).<br>b. <input type="checkbox"/> have been communicated by the International Bureau.<br>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.<br>d. <input type="checkbox"/> have not been made and will not be made.<br>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).<br>9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).<br>10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).<br><b>Items 11 to 20 below concern document(s) or information included:</b><br>11. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.<br>12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.<br>13. <input checked="" type="checkbox"/> A preliminary amendment.<br>14. <input checked="" type="checkbox"/> An Application Data Sheet under 37 CFR 1.76.<br>15. <input type="checkbox"/> A substitute specification.<br>16. <input type="checkbox"/> A power of attorney and/or change of address letter.<br>17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825.<br>18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4).<br>19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4). |  |   |

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

|  |              |   |         |  |    |
|--|--------------|---|---------|--|----|
| U.S. APPLICATION NO. (if known, see 37 CFR 1.5)<br><b>10/577167</b>  |              | INTERNATIONAL APPLICATION NO.<br>PCT/US2004/035874                            |         | ATTORNEY'S DOCKET NUMBER<br>701039-53522 |    |
| 20. Other items or information:<br>Exp. Mail Cert EV653005071US; Transmittal of Formal Drawings; Formal Drawings; Transfer of Seq. Listing; Statement Accompanying Seq. Listing; PAPER COPY-Seq. Listing; Forms PCT/IB/301, 304, 308s; PCT WO 2005/041877 coversheet; Form PCT/ISA/237; Form PCT/ISA/210; COPY-Refs. A1 and B1 and Return Receipt Postcard.  |              |   |         |  |    |
| The following fees have been submitted   |              |   |         | <b>CALCULATIONS</b> <b>PTO USE ONLY</b>  |    |
| 21. <input checked="" type="checkbox"/> Basic national fee (37 CFR 1.492(a))..... \$300  |              |   |         | \$ 300.00                                |    |
| 22. <input checked="" type="checkbox"/> Examination fee (37 CFR 1.492(c))  |              |   |         | \$ 200.00                                |    |
| If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..... \$0<br>All other situations..... \$200   |              |   |         |  |    |
| 23. <input checked="" type="checkbox"/> Search fee (37 CFR 1.492(b))   |              |   |         | \$ 100.00                                |    |
| If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..... \$0<br>Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority..... \$100<br>International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB..... \$400<br>All other situations..... \$500 |              |   |         |  |    |
| <b>TOTAL OF 21, 22 and 23 =</b>  |              |   |         | 600.00                                   |    |
| <input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)).<br>The fee is \$250 for each additional 50 sheets of paper or fraction thereof.  |              |   |         |  |    |
| Total Sheets   | Extra Sheets | Number of each additional 50 or fraction thereof (round up to a whole number) | RATE    |  |    |
| 66 - 100 =   | -34 /50 =    |   | x \$250 | \$ 70.00                                 |    |
| Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).  |              |   |         | \$ 130.00                                |    |
| CLAIMS   | NUMBER FILED | NUMBER EXTRA  | RATE    |  |    |
| Total claims   | 19 - 20 =    | 0   | x \$ 50 | \$ 0.00                                  |    |
| Independent claims   | 1 - 3 =      | 0   | x \$200 | \$ 0.00                                  |    |
| MULTIPLE DEPENDENT CLAIM(S) (if applicable)  |              |   | + \$360 | \$ 0.00                                  |    |
| <b>TOTAL OF ABOVE CALCULATIONS =</b>   |              |   |         | \$ 730.00                                |    |
| <input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.  |              |   |         | 365.00                                   |    |
| <b>SUBTOTAL =</b>  |              |   |         | \$ 365.00                                |    |
| Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).  |              |   |         | \$ 0.00                                  |    |
| <b>TOTAL NATIONAL FEE =</b>  |              |   |         | \$ 365.00                                |    |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property   |              |   |         | \$ 0.00                                  |    |
| <b>TOTAL FEES ENCLOSED =</b>   |              |   |         | \$ 365.00                                |    |
|  |              |   |         | Amount to be refunded:                   | \$ |
|  |              |   |         | Amount to be charged                     | \$ |

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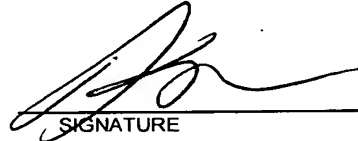
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- APR 26 2006 PTO
- a. ☐ A check in the amount of \$ \_\_\_\_\_ to cover the above fees is enclosed.
- b. ☒ Please charge my Deposit Account No. 50-0850 in the amount of \$ 365.00 to cover the above fees.  
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0850. A duplicate copy of this sheet is enclosed.
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

**NOTE:** Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

David S. Resnick  
Nixon Peabody LLP  
100 Summer Street  
Boston, MA 02110  
US



SIGNATURE

David S. Resnick/J. Amelia Feulner  
NAME

34,235/58,039

REGISTRATION NUMBER

10/577167

Practitioner's Docket No. 701039-53522

PATENT

IN THE UNITED STATES RECEIVING OFFICE

APR 26 2006

|                                     |                               |   |
|-------------------------------------|-------------------------------|---|
| PCT/US2004/035874                   | 28.10.2004<br>28 October 2004 | 29.10.2003<br>29 October 2003           |
| International<br>Application Number | International<br>Filing Date  | International Earliest<br>Priority Date |

**TITLE OF INVENTION: METHOD OF INHIBITING REJECTION  
FOLLOWING ORGAN TRANSPLANTATION**

**APPLICANT(S) FOR EO/DO:** Children's Medical Center Corporation  
**INVENTOR(S)/APPLICANT(S) FOR US:** David M. Briscoe et al.

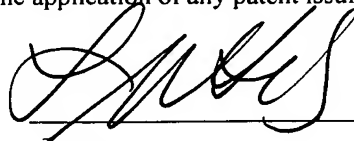
**VERIFIED CERTIFICATION OF EXPRESS MAILING DATE  
(INTERNATIONAL APPLICATION (37 C.F.R. section 1.10(c)))**

I declare that, on April 26, 2006 I deposited, with the United States Postal Service, in an envelope "Express Mail, Post Office to Addressee," bearing Label Number EV653005071US, addressed to the "MAIL STOP PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450," and having an express mail certification that I executed, the following papers:

1. Express Mail Certificate EV653005071US (1 pg.);
2. Transmittal Letter to the U.S. Receiving Office Concerning a Filing Under 35 U.S.C. 371 – page 3 in duplicate (4 pp.);
3. Application Data Sheet (3 pp.);
4. Preliminary Amendment (7 pp.);
5. Transmittal of Formal Drawings (1 pg.);
6. Formal Drawings (22 pp.);
7. Transfer of Sequence Listing (2 pp.);
8. Statement Accompanying Sequence Listing (1 pg.);
9. PAPER COPY - Sequence Listing (2 pp.);
10. Form PCT/IB/301 (3 pp.);
11. PCT/IB/Form 304 (1 pg.);
12. Form PCT/IB/308 (First and Second Notices) (2 pp.);
13. Published PCT WO 2005/041877 A3 (coversheet, 1 pg.);
14. Form PCT/ISA/237 – Written Opinion (4 pp.);
15. International Search Report - Form PCT/ISA 210 (4 pp.);
16. Information Disclosure Statement, including Form 08a (3 pp.);
17. COPY – References A1 and B1 cited in International Search Report;
18. Return Receipt Postcard.

A copy of these papers from the file of this application is attached.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application of any patent issuing thereon.



Date: April 26, 2006

Linda M. Ginsberg  
(type or print name of person certifying)

10/577167

Practitioner's Docket No. 701039-53522

PATENT

IN THE UNITED STATES RECEIVING OFFICE

APR 26 2006

|                                     |                               |   |
|-------------------------------------|-------------------------------|---|
| PCT/US2004/035874                   | 28.10.2004<br>28 October 2004 | 29.10.2003<br>29 October 2003           |
| International<br>Application Number | International<br>Filing Date  | International Earliest<br>Priority Date |

**TITLE OF INVENTION:**      **METHOD OF INHIBITING REJECTION FOLLOWING  
ORGAN TRANSPLANTATION**

**APPLICANT(S) FOR EO/DO:**      Children's Medical Center Corporation  
**INVENTOR(S)/APPLICANT(S) FOR US:**      David M. Briscoe et al.

**MAIL STOP PCT**  
**Commissioner for Patents**  
**P.O. Box 1450**  
**Alexandria, VA 22313-1450**

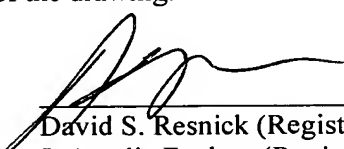
### TRANSMITTAL OF FORMAL DRAWINGS

Attached please find:

- (a)      the formal drawing(s) for this application.  
            Number of Sheets: 22

Each sheet of drawing indicates the identifying indicia suggested in § 1.84(c)  
on the reverse side of the drawing.

Date: April 26, 2006

  
\_\_\_\_\_  
David S. Resnick (Registration No. 34,235)  
J. Amelia Feulner (Registration No. 58,039)  
Nixon Peabody LLP  
100 Summer Street  
Boston, MA 02110  
617-345-6057

### CERTIFICATION UNDER 37 C.F.R. §§ 1.8(a) and 1.10\*

I hereby certify that, on the date shown below, this correspondence is being:

#### MAILING

☐ deposited with the United States Postal Service in an envelope addressed to the MAIL STOP PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

37 C.F.R. § 1.8(a)

☐ with sufficient postage as first class mail.

37 C.F.R. § 1.10\*

☒ as "Express Mail Post Office to Addressee"  
Mailing Label No. EY653005071US (mandatory)

Date: April 4, 2006

  
\_\_\_\_\_  
Signature

Linda M. Ginsberg

(type or print name of person certifying)